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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,810	07/25/2001	Martin M. Matzuk	P01925US1	2015
26271	7590	04/21/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/830,810	MATZUK ET AL.	
	Examiner	Art Unit	
	Anand U Desai, Ph.D.	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 11-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/23/02 &amp; 7/9/03</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group II, claims 2-10 in Paper filed on October 22, 2003 is acknowledged. Claims 1, and 11-57 are withdrawn from further consideration as being drawn to nonelected inventions. Claims 2-10 are currently pending, and are under examination.

### *Priority*

2. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e), and 120. The priority date is October 28, 1998 claiming priority to provisional application serial number 60/106,020. This application is a National Stage of PCT/US99/25209 filed October 28, 1999.

### *Claim Rejections - 35 USC § 101*

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The claims are directed to an isolated polynucleotide sequence designated as SEQ ID. NO: 1. The specification does not specifically address the activity or use of the polynucleotide, SEQ ID. NO: 1. On page 2, line 30 the polynucleotide is suggested to function as other oocyte specific genes. On page 3, starting at line 4 of the specification the polynucleotide is described in a general manner to relate to various cell proliferative or degenerative disorders, and infertility. On page 3, beginning on line 16, the specification describes the use of the polynucleotide as a reagent to

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study ovarian development and function. The specification also discloses that the polynucleotide can be used to screen for genetic mutations in components of signaling pathways that are associated with some forms of human infertility or gynecological cancers. On page 3, beginning on line 25 the polynucleotide is suggested to be used in the generation of mutant mice for the further study of oogenesis and/or folliculogenesis. The knockouts are suggested to provide key insights into the roles of the polynucleotide gene product in human female reproduction. On page 7, beginning on line 1, the specification states that based on the known activities of many other ovary specific proteins, it can be expected that the protein product from the polynucleotide will also possess biological activities that will make them useful as diagnostic and therapeutic reagents. On page 7, beginning on line 5, the specification suggests that based on similar expression patterns of the claimed novel polynucleotide and a growth differentiation factor-9, the protein product of the polynucleotide would function in a similar manner. On page 7, beginning on line 14, the specification suggests that since the protein product of the polynucleotide has similar tissue of origin as inhibin, both would possess similar biological activities. On page 7, line 23, the specification discloses that the protein of the polynucleotide may be useful as an indicator in prenatal screening procedures. On page 7, beginning on line 25, the specification suggests that the protein of the polynucleotide may function for the treatment of ovarian cancer. On page 19, beginning on line 2, the specification suggests that sequences complementary to the polynucleotide sequence claimed could be used in treatments of cell-proliferative disorders. On page 20, line 5, the specification teaches the use of the polynucleotide in gene therapy. On page 23, line 15, the specification states that the protein product of the polynucleotide could play a role in regulation of the menstrual cycle, and therefore, could be useful in various contraceptive

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regimens. On page 28, beginning on line 18, the specification discloses that the open reading frame of the polynucleotide product fails to demonstrate any structural motifs reminiscent of known proteins, suggesting that they will be functionally unique. These are not considered to be specific or substantial utilities for the polynucleotide. The method such as recombinant production of protein is not considered to be specific or substantial utility. These asserted utilities are broad and are not specific to the polynucleotide of SEQ ID. NO: 1. There is no disclosed signaling pathway associated with the polynucleotide of SEQ ID. NO: 1, and there is no disease or disorder correlated with the polynucleotide of SEQ ID. NO: 1. For example, on page 19, the passage does not disclose which cell-proliferative disorders will be treated with the polynucleotide of SEQ ID. NO: 1. Given that the specification does not disclose how to use the polynucleotide, a skilled artisan would not know how to use the polynucleotide. Thus, the specification fails to set forth a specific and substantial utility.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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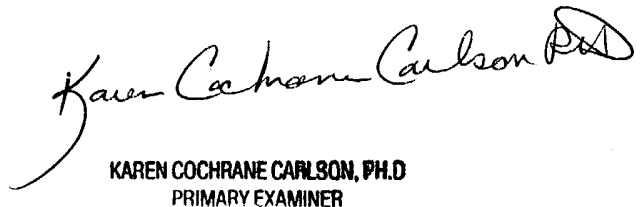
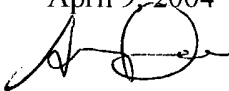
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (517) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 9, 2004



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER